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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,010

Applicant(s)

AUSTIN ET AL.

Examiner

Richard R. Shaffer

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,17-21,23-25,28-34 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,17-21,23-25,28-34,42-45,47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 18th, 2007 has been entered.

Election/Restrictions

Claim 46 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 25th, 2007.

Specifically, claim 46 is directed to the embodiment shown in Figure 19, whereas the embodiment shown in Figures 15-18 is the one previously elected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention. Claim 3 recites, "...the carriage is positioned **entirely** within the internal recess..." Applicant's carriage is not "entirely" within the recess, rather only the protrusions containing threaded openings 134B are, with the square-like platform being outside of the recess. The claims will be interpreted as requiring the carriage to substantially be located within the recess.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Pennig (US Patent 5,827,282).

Pennig discloses a system (**Figures 1-9**) comprising: a first member (**22**, shown in **Figure 3**); a second member/pivot arm (**11**, **Figure 1**) having a shaft (**6**) extending transversely (**se Figure 2**) in a fixed relationship (**when 12 is tightened**) with a circumferential groove (**15**); a pin clamp (**1**, **Figure 1**) attachable and detachable from the shaft (**6**); the pin clamp having a first jaw (**3**) and a second jaw (**2**); a hole is located in the first jaw to receive the shaft (**6**); bolts (**4**) are received in order to bias the two jaws together; a locator pin (**16**) is received within the groove to hold it into place; and the locator pin can be externally accessible for manual pushing or pulling to allow release of the shaft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 17 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faccioli et al (PCT Publication WO 00/40163) in view of Lee et al (US Patent 5,405,347).

Faccioli et al disclose an external fixation apparatus (**Figures 1-11**) and a method of treating a skeletal condition with the apparatus comprising: fixing first member (**3**) by pins (**5**) to the tibia; a pivot arm (**20** and **35** together) having an upper portion with a ball end (**29**, **Figure 2**) and a lower portion with a prong end (**60** -- only one side defining a single prong); an asymmetric pin clamp (**40**, **50**) coupled to and rotatable about the prong end through a lockable joint (interaction of **35** with **38**); the pin clamp fixed to a talus or calcaneus; and a push/pull mechanism (**35**) accessible externally for releasably coupling the pin clamp.

Faccioli et al disclose all of the claimed limitations except for carriage located within an internal recess defined by adjacent portions of the upper and lower portions, the carriage having a worm gear with two threaded holes and a keybolt located in each of the upper and lower portions to control movement in two transverse directions relative the longitudinal axis.

Lee et al teach (**Figures 1-11; Column 1, Line 15-55**) that prior art devices attempted to accommodate for the situation when a surgeon realizes a section of fractured bone is out of alignment and is thus required to correct the fixation system by pivotally linked fixator rods. Lee et al did not disregard the pivotal movement, but stated that lateral movement was an important motion to allow a surgeon to realign the fixation device without removing bone pins. Lee et al used a carriage (**52**) with a threaded hole (**57**) in conjunction with a worm gear (**threaded portion of 46**) and keybolt (**head 48 of 46**) to provide for lateral movement. It would have been obvious to one having ordinary skill in the art to provide for lateral motion through the use of a worm gear in order to better assist a surgeon in realignment of the fixation device thereby avoiding bone pin removal and re-insertion.

Lee et al however taught that the carriage, worm gear and keybolt were all rotatable about the longitudinal axis and thus capable of an infinite amount of axes of translation. Therefore, the use of a second worm gear (for movement in an additional lateral direction) was not taught.

It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, see *St. Regis Paper Co v Bemis Co.*, 193 USPQ 8. This is deemed relevant since applicant's invention merely serves a lesser function (two axes versus infinite) to which *In re Karlson*, 136 USPQ 184 states that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. Applicant wished to have two axes instead of infinite. It would have been obvious to one having ordinary skill in

the art to provide two worm gears should one only desire two axes for lateral motion by removing the rotatable motion along the longitudinal axis of the device.

The remaining design consideration to one having ordinary skill in the art at the time of invention would have been the location to place the worm gears and carriage in order to maintain all previous functionality of Faccioli et al (i.e. telescoping motion). Therefore, one having ordinary skill in the art would have reasonably concluded to place the device in either elements **3 or 20** of Faccioli et al in either a tandem design of including **52, 46 and 30** orientated as shown in **Figure 2** of Lee et al orientated facing opposite in order to be attached to opposite members or to provide the translation directly to the pre-existing carriage (**52**) orientated at a 90 degree offset (this final option resulting in a design matching the claimed invention).

Method steps directed towards coupling the pin clamp to the first member, moving the carriage within the recess, and rotating the pin clamp are all deemed inherent in the normal use of the device.

In regard to claim 32, such a method step is deemed a matter of obvious design choice to one having ordinary skill in the art at the time of invention because a surgeon would clearly have his/her own preference whether the first member or pin clamp is fixed first as well as applicant having no criticality for such a method step. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 44, 45, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig.

Pennig disclose all of the claimed limitations except for the located pin having enlarged knob, a spring partially surrounding and biasing the locator pin, and the locator pin having a snap connection with the groove (15).

It is well known in the art, that means for connecting elements together include threaded, interference/friction fit, detent, snap-fit and welded/glued connections. They are all known as equivalent means for connection with temporary connections (detent, threaded, snap-fit) known for allowing components to be modular and easy to clean. Snap-fit further have the benefits of giving the operator audible and tactile response signifying a completed connection as well as being quick to perform. It would have been obvious to one having ordinary skill in the art at the time of invention to provide a snap-fit connection between the pin (16) and groove (15) as a simple means for confirming a stable connection in a short time.

An enlarged gripping knob and a biasing spring are known structures in snap-fit connections in order to allow the operator to easily handle and release components when utilizing pin connections. It would have been a matter of mere design choice for one having ordinary skill in the art to select the structure as a predictable means of providing a snap-fit connection.

Claims 18, 19, 20, 21, 23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig in view of Lee et al.

Pennig discloses all of the claimed limitations except for carriage located within an internal recess defined by adjacent portions of the upper and lower portions, the carriage having a worm gear with two threaded holes, a keybolt located in each of the

upper and lower portions to control movement in two transverse directions relative the longitudinal axis and a bolt being received through the first and second jaws such that it interferes with the shaft and locks rotation of the pin clamp about the pivot arm.

As described previously, Lee et al teaches the use of a worm gear for lateral movement. It would have been obvious to one having ordinary skill in the art at the time of invention to provide to modify Pennig in the portion corresponding to element (7) in the same manner as Faccioli et al for the reasons listed previously.

Further, it would have been a matter of design choice to have bolt (17) pass through the first and second jaws (instead of just the first jaw) by allowing the second jaw (2) to have an extended portion to also receive element (17) since applicant has not stated any criticality for the bolt to pass through two jaw members instead of merely one. The end result is the same; the bolt interferes with the shaft and locks rotation of the device. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 24, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennig in view of Lee et al and in further view of Hoffman et al (US Patent Application 2002/0077629).

Pennig in view of Lee et al disclose all of the claimed limitations except for biasing elements that receive bolts (4) and are capable of biasing both jaws together. Hoffman et al teach (**Page 3, Paragraph 0028**) that coil springs (10 and 10') holds the plates partially apart (loose connection) in order to ease installation of the bone pins in-between the jaws. Further, the springs would bias the jaws in alignment by being placed within their cavities and inherently would bias them slightly together (if pulled beyond

their equilibrium point or if stretched and tied around the jaws). It would have been obvious to one having ordinary skill in the art at the time of invention to provide coil springs as taught by Hoffman et al to the device of Pennig in view of Lee et al in order to make it easier for the surgeon to install the bone pins within the pin clamp.

Response to Arguments

Applicant's arguments filed October 18th, 2007 have been fully considered but they are not persuasive. In regard to Faccioli et al, the examiner has more specifically defined what elements correspond to applicant's recited limitations to more clearly show how the prior art anticipates the claims. In regard to Penneg, all rejections have been modified to either read upon the newly claimed limitations or to better explain why certain structure is obvious (i.e. snap fit connection).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Richard Shaffer
December 3rd, 2007



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER